

REMARKS

The Office Action mailed June 19, 2006, has been received and reviewed. Claims 1, 3-10, and 14-16 are pending in the application. Claims 1, 3-10, and 14-16 stand rejected. Claims 1, 3, 4, 6, 7, 10, and 14-16 are amended herein. All amendments are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

Applicants note that the cover sheet of the Office Action mailed June 19, 2006, indicates that claims 1, 3-10, and 14-16 are rejected. However, applicants note that only rejections to claims 1, 3-5, and 9 are set forth in the body of the Office Action. Clarification is respectfully solicited.

As the five-month deadline for replying to the Office Action mailed on June 19, 2006 fell on a Sunday, submitted herewith is a Petition for Extension of Time (2 months) pursuant to 37 C.F.R. § 1.136(a).

Objection of Declaration under 37 C.F.R. § 1.131

Applicants kindly note the objection to the declaration of Dr. Montelaro. Applicants are currently conducting a detailed inquiry into the issues raised by the Examiner. Applicants further note that, in the interim, the outstanding provisional rejection regarding *Li et al. (J. virol. 2000, Vol. 74, No. 1, pp. 573-579)* (hereinafter “Li(B)”) is responded to hereinbelow.

35 U.S.C. § 112, second paragraph

Claims 1, 5, and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it was stated that Applicants did not identify where the deletion is located and which gene lacks expression. Applicants respectfully submit that the amendments to the claims overcome the rejections.

Although the applicants do not agree that any of the claims are indefinite, to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1 is amended to recite “a deletion in said open reading frame.” As such, applicants respectfully submit that claim 1, as amended, specifically identifies where the deletion is located, to wit “in said open reading frame.” Claim 1 is further amended to remove the recitation relating to gene expression.

Consequently, applicants respectfully submit that claim 1, as amended, can no longer be considered indefinite for failing to distinctly indicate which gene lacks expression. Therefore, applicants respectfully submit that the rejection to claim 1 under 35 U.S.C. § 112, second paragraph has been overcome. In addition, applicants respectfully submit that claims 5 and 9 are allowable, *inter alia*, as depending, directly or indirectly from allowable independent claim 1. As such, applicants respectfully request the withdrawal of the rejections of claims 1, 5, and 9 under 35 U.S.C. § 112, second paragraph, and reconsideration of same.

Rejections under 35 USC §102/ 103

A. Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Li(A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348). Applicants respectfully traverse the rejections as hereinafter set forth.

With regards to the 102(b) rejection, the Examiner alleges that Li(A) teaches “a genetically engineered EIAV construct . . . that comprises insertions of two redundant stop codons at positions G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methionine at position 18 is deleted.” Office Action mailed June 19, 2006, at page 4. Applicants respectfully traverse the rejection as hereinafter set forth.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 841 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully submit that claim 1, as amended, cannot be anticipated by Li(A) as Li(A) does not teach each and every element of claim 1. Specifically, claim 1, as amended, requires “two (2) stop codons in said open reading frame; *and* a deletion in said open reading frame.” (Emphasis added.) Applicants respectfully submit that where Li(A) teaches stop codons at G5 and G18, these are considered *substitutions* and not *deletions*. Li(A) is in agreement, noting at page 8344, right column, first full paragraph, that “[a] panel of clones with *substitutions* that introduce one or more premature stop codons . . . or with a *deletion* of the first 5 nucleotides of S2 . . . were produced.” (emphasis added). A similar passage appears in ¶ [0046] of the Specification as published. As such, applicants respectfully submit that both Li(A) and the Specification teach that the introduction of

stop codons (to replace other codons) are properly referred to as *substitutions* and that a *deletion* refers to a situation where nucleotides are removed and not replaced. Applicants respectfully submit that the *substitutions* used to create stop codons in Li(A) are not *deletions*. Consequently, applicants respectfully submit that one of ordinary skill in the art would understand given the teachings of the specification and of Li(A) that creation of stop codons as taught by Li(A) are *substitutions* and not *deletions*. As such, applicants respectfully submit that Li(A) does not teach a single construct having both two stop codons and a deletion as recited by claim 1.

In view of the foregoing, applicants respectfully submit that Li(A) cannot anticipate claim 1, as amended, as Li(A) does not teach each and every element of claim 1. Consequently applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) and reconsideration of same.

Further as claims 3 and 4 depend from claim 1, applicants respectfully assert that they are allowable, *inter alia*, as depending from an allowable independent base claims. As such, applicants respectfully request the withdrawal of the rejections of claim 3 and 4 under 35 U.S.C. § 102(b) and reconsideration of same.

With regard to the 103(a) rejection, the Examiner alleges that “it would have been obvious for a person with ordinary skill in the art to be motivated for making a recombinant EIAV construct that comprises deleting the first 5 nucleotides of the S2 gene in addition to the insertion of two redundant stop codons in the S2 gene because both mutations have been approved to only inactivate the S2 gene expression without interrupting envelope protein expression of the EIAV gene.”

To establish a *prima facie* case of obvious there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully submit that the obviousness rejection over Li(A) is improper as the Examiner has not provided adequate motivation to modify the teachings of the reference. Contrary to the Examiner’s assertion, applicants respectfully submit that one of skill in the art would not be motivated to combine the 5 nucleotide deletion of Li(A) with the insertion of two redundant stop codons. Li(A) notes that the redundant stop codon construct and the 5 nucleotide deletion construct performed equally well in terms of replication kinetics. Li(A) at

FIG. 2. Further, Li(A) notes that neither construct showed any reversion. *Id.* at page 8345, first column, end of 1st paragraph. As both constructs perform equally well and both show no reversion, applicants respectfully submit that there is no motivation for one of ordinary skill in the art to combine the constructs to arrive at the presently claimed invention. Consequently, applicants respectfully submit that the Examiner has not made a *prima facie* case of obviousness and that the rejections of claims 1, 3, and 4 under 35 U.S.C. § 103(a) over Li(A) are improper. As such, applicants respectfully request the withdrawal of the rejections of claims 1, 3, and 4 under 35 U.S.C. § 103(a) over Li(A) and reconsideration of same.

B. Claims 1, 3, and 4 stand provisionally rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Li(B) (J. Virol. Jan. 2000, Vol. 74, No. 1, pp. 573-579). Applicants respectfully traverse the rejections as hereinafter set forth.

At page 5 of the Office Action mailed June 28, 2005, the Examiner asserts that “Li(B) discloses an immunogenic composition comprising the genetically engineered EIAV construct EIAV.2M/X as described [in Li(A)]” and that “therefore the claimed invention is anticipated by [Li(B)].” Applicants hereby incorporate the remarks made *supra* relating to Li(A) and note that Li(B) provides no additional teachings over Li(A) with regard to the present invention. As such, for the reasons enumerated *supra* with regard to Li(A), applicants respectfully request the withdrawal of the rejections of claims 1, 3, and 4 under 35 U.S.C. § 102(a) and reconsideration of same.

C. Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent 6,528,250 to Montelaro et al. Applicants respectfully traverse this rejection.

U.S. Patent 6,528,250 to Montelaro et al. (“the ‘250 Patent”) was filed on September 9, 2000, the same date as U.S. Patent 6,585,978 to Montelaro et al. (“the ‘978 Patent”). The current application claims the benefit of the ‘978 Patent. The ‘978 Patent discloses the subject matter relied upon by the Examiner (Office Action, page 6) including the insertion of two redundant stop codons (*see, e.g.*, ‘978 Patent, col. 4, line 36- col. 5, line 10) and the deletion of some nucleotides of the S2 gene or deletion of the DU gene (*Id.*, col. 3, lines 39-46; col. 4, line 36- col.

5, line 32). Accordingly, the '250 Patent should be removed as a prior art reference. Reconsideration and withdrawal of the rejection is requested.

D. Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Li(A) in view of Lichtenstein et al. (J. Virol. 1995, Vol. 69, No. 5, pp. 2881-2888).

The discussion of Li(A) *supra* is incorporated herein. The Examiner asserts that Lichtenstien teaches "a method for deleting the EIAV DU gene without influencing the expression of the envelope protein of EIAV." Office Action mailed July, 19, 2006, at page 7. The Examiner further asserts that "it would have been obvious for a person with ordinary skill in the art to make a construct that comprises both S2 gene and DU gene mutations made by the methods taught by Li(A) and Lichtenstien, wherein the mutated EIAV construct is still able to replicate and express its normal envelope protein." Applicants respectfully traverse the rejection as hereinafter set forth.

As noted *supra*, Li(A) does not teach or suggest the combination of two stop codons in the S2 gene open reading frame in conjunction with a deletion in the S2 open reading frame as recited by claim 1 as amended. The teachings of Lichtenstien relate to deletions in the DU gene and are thus unrelated to a deletion in the S2 open reading frame. As such, applicants respectfully submit that Lichtenstien provides no further teaching to remedy the deficiencies of Li(A) as noted *supra*. As such, applicants respectfully submit that the combination of Li(A) and Lichtenstien cannot make obvious claims 1, 3, and 4. Consequently, applicant respectfully request the withdrawal of the rejections of claims 1, 3, and 4 under 35 U.S.C. § 103(a) over Li(A) in view of Lichtenstien and reconsideration of same.

E. Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Li(A) in view of U.S. Patent 6,528,250 to Montelaro et al.

The discussion of Li(A) *supra* is incorporated herein. As stated herein, U.S. Patent 6,528,250 to Montelaro et al. ("the '250 Patent") was filed on September 9, 2000, the same date as U.S. Patent 6,585,978 to Montelaro et al. ("the '978 Patent"). The current application claims the benefit of the '978 Patent. The '978 Patent discloses the subject matter relied upon by the

Examiner (Office Action, page 8)(*Cf.* FIG. 1 in the '250 Patent and FIG. 1 in the '978 Patent). Accordingly, the '250 Patent should be removed as a prior art reference. As the '250 Patent is not available to cure the deficiencies of Li (A), the proposed combination cannot render the claims obvious. Reconsideration and withdrawal of the rejection is requested.

F. Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Li(A) in view of Kingsman (WO 99/32646 A1). Applicants respectfully traverse the rejection as hereinafter set forth.

The discussion of Li(A) *supra* is incorporated herein. Applicants note that where Kingsman discusses deletion of the S2 gene, it deletes from nucleotide positions 5345 to 5397 and that this deletion removes the ATG start codon of S2 and the start codon of the envelope gene. Kingsman at page 40, lines 23-25.

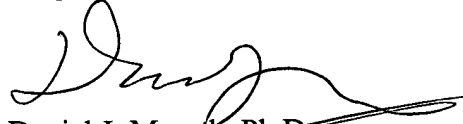
The prior art reference, or references when combined, must teach or suggest each and every element of the claim. *In re Vaeck*, 947 F.2d. Applicants respectfully submit the references, when combined, do not teach each and every element of claim 1 as amended. Kingsman teaches the deletion of nucleotide positions 5345 to 5397, which includes the stop codons that Li(A) would insert into the S2 open reading frame. As such, applicants respectfully submit that the combination of Li(A) and Kingsman cannot make obvious claims 1, 3, and 4 as the deletion taught in Kingsman would cause the resulting construct to no longer contain two stop codons in the open reading frame as required by claim 1. Consequently, applicant respectfully request the withdrawal of the rejections of claims 1, 3, and 4 under 35 U.S.C. § 103(a) over Li(A) in view of Kingsman and reconsideration of same.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Examiner is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Serial No. 10/627,568

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dan Morath', with a long horizontal flourish extending to the right.

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